CONSULTATION

PHARMAC
Pharmaceutical Management Agency

01 April 2015

Proposal to list intravenous nicardipine

PHARMAC is seeking feedback on a proposal to list nicardipine hydrochloride injection 2.5 mg per ml, 10 ml vial in Part II of Section H of the Pharmaceutical Schedule from 1 June 2015.

In summary, this proposal would result in nicardipine hydrochloride injection being listed for paediatric patients subject to restriction criteria.

Details of the proposal can be found on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 17 April 2015** to:

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Therapeutic Group Manager
PHARMAC
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Wellington 6143

Email: chris.little@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

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Details of the proposal

Nicardipine hydrochloride injection would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 June 2015 as follows:

NICARDIPINE HYDROCHLORIDE
Inj 2.5 mg per ml, 10 ml vial

Nicardipine hydrochloride would be funded subject to the following restriction criteria in Part II of Section H of the Pharmaceutical Schedule:

Restricted
Anaesthetist or intensivist
Both:
1. Patient is a paediatric patient; and
2. Any of the following:
   2.1. Has hypertension requiring urgent treatment with an intravenous agent; or
   2.2. Has excessive ventricular afterload; or
   2.3. Is awaiting or undergoing cardiac surgery using cardiopulmonary bypass.

Background

PHARMAC received a clinician application for nicardipine hydrochloride to be listed for the treatment of hypertensive Paediatric Intensive Care Unit patients and, for the treatment of infants and neonates undergoing cardiac surgery using cardiopulmonary bypass. Nicardipine hydrochloride is a potent vasodilator given by intravenous infusion with the potential to cause serious life-threatening hypotension. The applicant advised that it would only be used in patients who are in the operating room or the intensive care unit, so would only be given by medical staff working in those areas.

The applicant states there is no other drug that can be safely used for vasodilatation during bypass in infants. Phentolamine has been withdrawn from the market in the last six months, so the applicant considers some of these patients are missing out on appropriate treatment with the risk of brain injury and other organ dysfunction post cardiopulmonary bypass. The applicant indicates that sodium nitroprusside is not a suitable alternative as it is associated with serious adverse effects in neonates and infants with impaired renal function, which frequently co-exists with cardiac disease, and that intravenous labetolol is not appropriate for use in patients with impaired ventricular function.

PHARMAC sought clinical advice from both the Cardiovascular and Analgesic Subcommittees of PTAC which supported the proposed paediatric use and agreed that nicardipine hydrochloride is not required for use in adult patients because there are adequate listed alternatives for them currently.

We note that nicardipine hydrochloride is not a Medsafe-registered treatment in New Zealand and PHARMAC has not entered into an agreement for the supply of this product at an agreed price. We understand the usage would be very low, such that the financial impact of this proposed listing would be less than $5k per year.